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EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,577	UCHIDA ET AL.	
	Examiner	Art Unit	
	TAEYOON KIM	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,17-21,24-29,32-34 and 36-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,17-21,24-29,32-34 and 36-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 14, 17-21, 24-29, 32-34 and 36-40 are pending.

Response to Amendment

Applicant's amendment and response filed on 7/17/2008 has been received and entered into the case.

Claims 1-13, 15, 16, 22, 23, 30, 31 and 35 are canceled, claims 36-40 are newly added, and claims 14, 17-21, 24-29, 32-34 and 36-40 are pending and have been considered on the merits. All arguments have been fully considered.

Response to Arguments

In the response to the claim rejection under 35 U.S.C.§103, applicant argued that the paper-like material of Greenawalt et al. is quite distinct from a non-woven fabric of the present invention. This argument is not persuasive. The claimed limitation of interest is "non-woven fabric". There is no further limitation to the non-woven fabric. Greenawalt et al. teach a process of making the hemostatic composition using a paper-making process, and this method is referred as "forming fabric". Since it is clearly not woven product, and the reference teaches it is a kind of fabric, the composition of Greenawalt et al. is surely considered as "non-woven fabric". The term "fabric" is understood as a material made of fibers, and clearly the material used in Greenawalt et al. is fibers (PGA), and the composition of Greenawalt et al. is non-woven since the paper-making process does not involve weaving.

Further, applicant argued that the instant invention is not an integrated sheet material as taught by Greenawalt et al. However, such limitation is not disclosed in the

current claims.

Applicant also argued that Greenawalt et al. do not disclose or suggest that PGA/thrombin and fibrinogen are separated from each other and combined together only when put to use. This argument is not persuasive based on the disclosure of Greenawalt et al. Greenawalt et al. clearly teach PGA/thrombin/fibrinogen and PGA/thrombin as applicant indicated. Applicant's attention is directed to column 8, lines 43-51 where Greenawalt et al. clearly teach one of the desired combinations of precipitates is thrombin/biopolymer (PGA) and fibrinogen, indicating that thrombin/biopolymer and fibrinogen are separate precipitates. Greenawalt et al. also disclose a kit having multiple hemostatic compositions, preferably wherein each is provided in a separate package (col. 6, lines 51-55). Considering that the combining thrombin and fibrinogen to activate fibrinogen to fibrin is well known in the art, it would have been obvious to a person of ordinary skill in the art to combine these separately packaged compositions (PGA/thrombin and fibrinogen) prior to use to activate fibrinogen to fibrin.

With regard to the claim interpretation of claim 28, applicant traverses that the examiner's position to consider "lyophilizing" as a process limitation is incorrect, quoting In re Luck et al.

The examiner agrees that lyophilizing step would provide a structural limitation to the nonwoven fabric of the claimed invention. However, the hemostatic material of Greenawalt et al., which is made by a process of paper-making, is in a dried state (col. 5, lines 12-18), and it is well known in the art that lyophilization is an alternative way of

drying step, and Greenawalt et al. also disclose that the active components can be lyophilized in separate layers as known in the art (col. 2, lines 20-25). Therefore, it would have been obvious to a person of ordinary skill in the art to try a lyophilization step for the drying step in making hemostatic compound material of Greenawalt et al. Since the limitation does not clearly impart distinctive structural characteristics to the final product, the structure implied by the process steps would not be required to be considered. Whether or not the product being lyophilized vs. air-dried, the material of Greenawalt et al. is considered substantially similar, if not the same, as the claimed invention.

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Applicant argued that there is no clear inherency proved by the examiner that the so-called “paper-like material” of Greenawalt et al. would have elasticity. In the office action, the examiner cited Ikada et al. which teach the property of PGA having elasticity and flexibility, and since the material is made of PGA, it is inherent property of the paper-like material having the characteristics of PGA and thus, expected to have elasticity and flexibility.

In the response to the claim rejection under 35 U.S.C.§112 based on Sugitachi et al. in view of Roth in further view of Greenawalt et al., applicant argued that Sugitachi et al. is a wound protecting and a healing material rather than a hemostatic material. This is not persuasive because the intended use of wound protecting includes prevention of bleeding (hemostat) and thus, the intended use of Sugitachi et al. is not different from the claimed purpose. Even if the intended use of Sugitachi et al. is considered different from the claimed invention, the material of Sugitachi et al. is capable as a hemostatic material because the same materials functioning in stopping the bleeding (i.e. thrombin and fibrinogen) are present in the material of Sugitachi et al. as the claimed invention.

Applicant asserted that the teaching of Roth (secondary reference) is irrelevant because "a physical structure” where hemostasis may be achieved by appropriately receiving blood. This assertion is not persuasive. It is clear that both Sugitachi et al. and Roth teach hemostatic materials, and the fabrics utilized in both materials are PGA. Thus, the intended use and the material used for the fabrics are the same between two teachings and thus they are clearly related. The difference is whether the fabric material being non-woven. Since the material of Roth is capable of the same purpose of

hemostasis as the material of Sugitachi et al., it would have been obvious to person of ordinary skill in the art to try the fabric (felt) of Roth as an art-recognized equivalent or suitable alternative to the fabric of Sugitachi et al.

Applicant further argued that Sugitachi et al.'s material lacks fibrinogen and the terms “stopping bleeding” and “wound healing” are two distinct concepts.

This argument is not persuasive. It is acknowledged that the hemostatic material of Sugitachi et al. do not particularly contain fibrinogen, rather it utilizes thrombin and Factor XIII to stabilize fibrin from the subject's body. This was also discussed in the previous office action (p.10-11). However, as discussed in the previous office action, it would have been obvious to a person of ordinary skill in the art to use fibrinogen in addition to the material of Sugitachi et al. As discussed above, and also disclosed by Sugitachi et al., the term "wound healing" includes "stop bleeding" since the main action of the material of Sugitachi et al. is to form stable fibrin based on the action of thrombin and Factor XIII on wound sites, which is the same as the claimed invention. These blood coagulation factors are extremely well known in the art to be involved in stopping bleeding.

Applicant argued that it would be risky to have a high level of fibrinogen since it would deter wound healing. This is merely the argument of counsel and is unsupported by evidence or declarations of those skilled in the art. Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See M.P.E.P. § 2129 and § 2144.03 for a discussion of admissions as prior art. Counsel's arguments cannot take the place of objective evidence. *In re Schulze*,

145 USPQ 716 (CCPA 1965); *In re Cole*, 140 USPQ 230 (CCPA 1964); and especially *In re Langer*, 183 USPQ 288 (CCPA 1974). See M.P.E.P. § 716.01(c) for examples of attorney statements that are not evidence and that must be supported by an appropriate affidavit or declaration.

Applicant also argued the elasticity of the Sugitachi et al.'s material, and asserted that the elastic property would not be determined solely by the sameness of the material but rather would vary depending on composition or amount of each of a protein, and additive and the like even if the same sheet material were to be processed. Again, this is merely the argument of counsel and is unsupported by evidence or declarations of those skilled in the art. Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. It is the examiner's position that the intrinsic property of PGA would provide elasticity to the material made of PGA as evidenced by Ikada et al. (see above). Furthermore, since the material of fabrics of Sugitachi et al. and Roth is the same as the claimed invention, it is expected that the materials of Sugitachi et al. or Roth made of PGA would have the same property as the claimed non-woven fabrics.

Finally, applicant argued that even if the references were obviously combinable, they do not lead to the use of a non-woven fabric of PGA, an important characteristic of the present invention.

This is not correct analyses of the references. Sugitachi et al. clearly teach that non-woven fabrics can be the wound healing material (col. 1, lines 49-55) and Roth also teaches the non-woven polyglycolic acid (PGA) felt (col. 12, lines 18-33). Thus, the

references clearly teach “non-woven fabric of PGA” in a hemostatic and/or wound healing materials.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation of “needle-punching fabric" in the current claims does not have proper support from the specification, and thus introduces a new matter to the application.

In amended cases, subject matter not disclosed in the original application is sometimes added and a claim directed thereto. Such a claim is rejected on the ground that it recites elements without support in the original disclosure under 35 U.S.C. 112, first paragraph, *Waldemar Link, GmbH & Co. v. Osteonics Corp.* 32 F.3d 556, 559, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994); *In re Rasmussen,* 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). See MPEP § 2163.06 - § 2163.07(b) for a discussion of the relationship of new matter to 35 U.S.C. 112, first paragraph. New matter includes not only the addition of wholly unsupported subject matter, but may also include adding

specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method. See MPEP § 608.04 to § 608.04(c). See *In re Wertheim,* 541 F.2d 257, 191 USPQ 90 (CCPA 1976) and MPEP § 2163.05 for guidance in determining whether the addition of specific percentages or compounds after a broader original disclosure constitutes new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21, 24-28 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenawalt et al. (US 6,056,970) in light of Ikada et al. (US 4,882,162).

Greenawalt et al. teach a kit comprising hemostatic compounds such as

thrombin, fibrinogen, Factor XIII, protease inhibitors and calcium chloride, along with a bioabsorbable synthetic polymer (nonwoven fabric) made of polyglycolide (polyglycolic acid; PGA)(columns 2-4).

Greenawalt et al. also teach thrombin and fibrinogen are derived from human plasma or synthetic forms produce by recombinant DNA technology (column 3, lines 52-64).

Greenawalt et al. also teach the PGA containing thrombin by mixing thrombin and PGA in organic solvent and then drying the combination (see Example 17).

Although Greenawalt et al. do not particularly teach the drying step being lyophilization, it is well known in the art that lyophilization is an alternative way of drying step, and Greenawalt et al. also disclose that the active components can be lyophilized in separate layers as known in the art (col. 2, lines 20-25). Therefore, it would have been obvious to a person of ordinary skill in the art to try a lyophilization step for the drying step in making hemostatic compound material of Greenawalt et al.

Although the composition comprising PGA/thrombin described above does not contain fibrinogen, it is well known in the art that activation of fibrinogen to fibrin by thrombin is required for hemostatic material, and Greenawalt et al. teach a two component system of fibrin glue, which comprises thrombin and fibrinogen separately and used together prior to application (see column 1, lines 19-38). Therefore, it would have been obvious to a person of ordinary skill in the art to add fibrinogen in the PGA/thrombin composition of Greenawalt et al. at the time of using the hemostatic composition for stopping bleeding and/or sealing wounds. By the combining fibrinogen

to the PGA/thrombin of Greenaswalt et al., the limitation of step (1) of claim 14 is inherently met by the reference.

Greenawalt et al. teach a hemostatic kit containing multiple hemostatic compositions in a separate package (column 6, lines 51-55).

Greenawalt et al. also teach the composition can include other components to provide stability, strength and flexibility (see column 15, lines 25-27).

Claim 21 has a transitional phrase of "consisting essentially of".

M.P.E.P. § 2111.03 clearly indicates that the transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). “A ‘consisting essentially of’ claim occupies a middle ground between closed claims that are written in a consisting of’ format and fully open claims that are drafted in a ‘comprising’ format.” *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998), *et al.* For the purposes of searching for and applying prior art under 35 U.S.C. §§ 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256

(CCPA 1964) *et al.* Since the specification in this case does not particularly point out the basic and novel characteristics of the claimed composition, "consisting essentially of" in claim 21 has been interpreted as "comprising" for the purpose of art rejections.

With regard to the limitation in claim 28, the claim contains a product-by-process limitation. The hemostatic material of Greenawalt et al., which is made by a process of paper-making, is in a dried state (col. 5, lines 12-18), and it is well known in the art that lyophilization is an alternative way of drying step, and Greenawalt et al. also disclose that the active components can be lyophilized in separate layers as known in the art (col. 2, lines 20-25). Therefore, it would have been obvious to a person of ordinary skill in the art to try a lyophilization step for the drying step in making hemostatic compound material of Greenawalt et al. Since the limitation does not clearly impart distinctive structural characteristics to the final product, the structure implied by the process steps would not be required to be considered. Whether or not the product being lyophilized vs. air-dried, the material of Greenawalt et al. is considered substantially similar, if not the same, as the claimed invention.

M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re*

Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

The structural limitation provided by the process steps of claim 28 is lyophilization. However, as discussed above, lyophilization of the material of Greenawalt et al. is obvious to a person of ordinary skill in the art.

With regard to the limitation to the hemostatic kit wherein Factor XIII being included in a container comprising fibrinogen, although Greenawalt et al. teach Factor XIII being an additional component in the hemostatic composition, and a hemostatic kit comprising multiple hemostatic component in a separate package (see column 6, lines 53-55), the reference does not specifically teach factor XIII being in a container comprising fibrinogen. Greenawalt et al. disclose that Tisseel™ comprises two components, and one of which is fibrinogen component including factor XIII (see column 1, lines 26-28). Therefore, it would have been obvious to a person of ordinary skill in the art to add Factor XIII in a container comprising fibrinogen in order to prevent fibrinolysis.

Although Greenawalt et al's product is described as "paper-like material," it is made of PGA (see Example 17), which would provide sufficient elasticity and flexibility as evidenced by Ikada et al. (see column 3, lines 51-65). Therefore, the PGA fabric of Greenawalt et al. would have inherent elasticity and flexibility to be formed into any shape. Unless applicant provides clear evidence that the composition of Greenawalt et al. does not possess the same elasticity and flexibility of the claimed invention, the examiner takes the position that the product of Greenawalt et al. would have the same property as the current invention.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made especially in the absence of evidence to the contrary.

Claims 14, 17-21, 24-29, 32-34 and 36-40 are rejected under 35 U.S.C. 103(a)

as being unpatentable over Sugitachi et al. (US 4,265,233) in view of Roth (US 3,937,223) in further view of Greenawalt et al. (supra).

Sugitachi et al. teach an absorbable material such as polyglycolic acid (PGA) comprising thrombin, and a process of making such is by dipping the material in saline solution of thrombin and then lyophilized (see Examples 2 and 6).

Sugitachi et al. also teach the absorbable material being non-woven fabric (col. 1, lines 49-55).

Roth teaches a hemostatic felt made of PGA (see Abstract). Roth also teaches PGA felt (non-woven fabric) having flexibility to conform readily to the surface of a bleeding wound (see Abstract).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace the absorbable material of Sugitachi et al. with the PGA felt of Roth.

The skilled artisan would have been motivated to make such a modification because the PGA felt of Roth is considered as an art-accepted equivalent for the same purpose of stopping bleeding and/or wound healing as the absorbable material (non-woven fabrics) taught by Sugitachi et al., which would be made of the same material, PGA.

M.P.E.P. §2144.06 states “In re Scott, 323 F.2d 1016, 139 USPQ 297 (CCPA 1963) (Claims were drawn to a hollow fiberglass shaft for archery and a process for the production thereof where the shaft differed from the prior art in the use of a paper tube as the core of the shaft as compared with the light wood or hardened foamed resin core

of the prior art. The Board found the claimed invention would have been obvious, reasoning that the prior art foam core is the functional and mechanical equivalent of the claimed paper core. The court reversed, holding that components which are functionally or mechanically equivalent are not necessarily obvious in view of one another, and in this case, the use of a light wood or hardened foam resin core does not fairly suggest the use of a paper core.); Smith v. Hayashi, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.)."

Although Sugitachi et al. in view of Roth do not teach the material comprising fibrinogen, it would have been obvious to a person of ordinary skill in the art to use fibrinogen separately or together with thrombin/PGA fibers of Sugitachi et al. in view of Roth, because it is notoriously well known in the art that the role of thrombin is to activate fibrinogen to fibrin to form a fibrin network, and fibrinogen is commonly added to thrombin or visa versa. For example, a fibrin sealant, Tisseel™, disclosed by Greenawalt et al. comprises two-component system: fibrinogen component and thrombin component, and fibrinogen component comprising Factor XIII, to be mixed before the use the system (see column 1, lines 20-30). Thus, a person of ordinary skill

in the art would recognize that additional fibrinogen comprising Factor XIII taught by Greenawalt et al. applied to the thrombin/PGA felt of Sugitachi et al. in view of Roth before the use of thrombin/PGA felt to a wound site would enhance and/or facilitate the formation of fibrin network, instead of utilizing fibrinogen present in the plasma of a patient being treated with a reasonable expectation of success.

Furthermore, since the use of fibrinogen along with thrombin is well known in the art as a hemostatic composition, it would have been obvious to a person of ordinary skill in the art to try fibrinogen applied to the thrombin/PGA felt of Sugitachi et al. in view of Roth prior to the use of the felt to a wound site to stop bleeding with reasonable expectation of success in using the thrombin/PGA felt along with fibrinogen/Factor XIII of Greenawalt et al.

The Supreme Court recently states in KSR v. Teleflex (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."

With regard to the elastic property of the hemostatic material of the current

invention, the hemostatic felt made of PGA comprising thrombin taught by Sugitachi et al. in view of Roth would have inherently possessed the same property as the claimed invention because the material of the references is considered the same or substantially identical to the claimed invention.

M.P.E.P. § 2112 recites, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established." *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

With regard to the hemostatic kit of the current invention, Greenawalt et al. teach a hemostatic kit comprising multiple hemostatic compositions in a separate package. It is well known in the art hemostatic compositions are packaged in a form of kit as shown by Tisseel™ (see column 1, lines 20-22) and the teaching of Greenawlat et al. (see column 6, lines 51-59).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try to prepare the hemostatic materials of Sugitachi

et al. in view of Roth (i.e. thrombin/PGA felt) along with fibrinogen/Factor XIII of Tisseel™ disclosed by Greenawalt et al. in a format of a kit. See KSR v. Teleflex (550 US82 USPQ2d 1385, 2007).

With regard to the limitation drawn to the non-woven fabric being made by needle-punching in claims 36-40, Roth teaches that an uncrimped fiber gives good results if needle punched (col. 5, lines 20-25), and thus it would have been obvious to a person of ordinary skill in the art to use a non-woven felt made by needle-punched fibers in the hemostatic material of Sugitachi et al. in view of Roth in further view of Greenawalt et al.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Taeyoon Kim